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EXAMINER

GUZO, DAVID

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Detailed Action

Election/Restriction

Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/13/06.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Avarbock et al. in view of Ojha et al.

This rejection is maintained for reasons of record in the previous Office Action (mailed 3/27/08) and for reasons outlined below.

Applicants have responded to this rejection by amending the claim to more particularly define the nature of the 200bp promoter fragment and asserting that Avarbock et al. does not indicate that the *relA/SpoT* promoter in *M. tuberculosis* is located in the intergenic region immediately upstream of the *relA/SpoT* coding region. Applicants assert that Avarbock et al. seems to indicate that transcriptional readthrough from the *apt* promoter may occur as in *S. coelicolor*. Applicants argue that Avarbock et

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al. does not define the location of the *apt* promoter in *M. tuberculosis* and theorizes that the point of origination of transcriptional readthrough may be beyond 200bp. Applicants further assert that Avarbock et al. teaches only that transcriptional readthrough may occur in *M. tuberculosis* and does not teach or suggest the location of the *relA* or *apt* promoters in *M. tuberculosis*, let alone render the 200bp proximal upstream region the obvious promoter region.

Applicant's arguments filed 7/28/08 have been fully considered but they are not persuasive. A fair reading of the Avarbock et al. reference indicates that the *M. tuberculosis relA/SpoT* gene may be under control of multiple promoters and that said promoter(s) may be in the intergenic region upstream of the *relA/SpoT* coding region and/or may be in the *apt* promoter (readthrough transcription). In any event, the region upstream of the *M. tuberculosis relA/SpoT* gene was characterized in the prior art, was compared with similar regions in other microorganisms, and the locations of the putative promoter(s) determined. Applicants merely determined that one of the putative promoter regions (the sequences immediately upstream of the *relA/SpoT* coding region) had promoter activity. The claimed 200bp sequence encompasses the intergenic region between the *apt* and *relA/SpoT* coding regions. The claimed promoter would have been obvious because the ordinary skilled artisan would have had good reason to pursue the known regions upstream of the *relA/SpoT* coding region with putative promoter activity and this pursuit would have been within his or her technical grasp given the teachings of the prior art and the technical skill of the ordinary skilled artisan. If this pursuit leads to the anticipated success, it is likely the product not of innovation

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but of ordinary skill and common sense. Also, since there existed a finite number of identified, predictable solutions (i.e. putative promoter regions such as the intergenic region immediately upstream of the *relA/SpoT* coding region), the ordinary skilled artisan would have had a reasonable expectation of success in isolating the promoter (See *KSR International Co. v. Teleflex Inc.*, 550 U.S.---, 82 USPQ2d 1385 (2007) and *Pfizer v. Apotex*, 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007)).

Claims 24-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Avarbock et al. in view of Ojha et al. and further in view of Hemming et al.

This rejection is maintained for reasons of record in the previous Office Action.

Applicants' traverse this rejection by indicating that the present amendment and remarks provided with respect to claim 23 are believed to render the rejection of dependent claims 24-28 moot.

In response, the examiner reiterates the arguments presented in the above 103(a) rejection of claim 23. For the reasons stated above and for reasons of record, the rejection stands.

Any rejections not repeated in this Office Action are withdrawn.

Claim 29 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low, Ph.D., can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 3, 2008

/David Guzo/
Primary Examiner
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